

**REMARKS**

Claims 1-24 were examined. New claims 25-30 have been added to further describe patentable aspects of the invention.

Applicants thank the Examiner for acknowledging the claim for priority under 35 U.S.C. § 119, and receipt of a certified copy of the priority document.

Applicants also thank the Examiner for considering the references cited with the Information Disclosure Statements filed October 15, 2003 and March 16, 2004.

**I. Formal Matters**

**A. Drawings**

On page 2 of the Office Action, the Examiner indicates that the drawings have been objected to under 37 C.F.R. § 1.83(a). In particular, the Examiner asserts that the distribution image of claims 21-23 must be shown in a drawing or the feature canceled from the claims. However, Applicants note that the distribution image is shown in Figure 19 and is described in the specification. Therefore, Applicants traverse this objection.

Figure 19 shows an example of a distribution image PD. On page 69, line 17-page 70, line 6, the distribution image PD is described as representing a distribution of degrees of certainty about malignancy in the image P. The distribution image is also described as being displayed by being superimposed upon the image P, as shown in Figure 19 (Page 72, line 8-Page 73, line 19). Therefore, the drawings do show the feature of the distribution image. Applicants respectfully request the withdrawal of this objection.

## **B. Specification**

The Examiner also objects to the specification for not being written in “full, clear, concise, and exact terms”, as required by 35 U.S.C. § 112, first paragraph. However, Applicants believe that the specification is written in compliance with 35 U.S.C. § 112 first paragraph and traverse this objection.

In order to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. “[T]he ‘essential goal’ of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed.” *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Applicants submit that the specification is sufficiently clear that one skilled in the art would understand that the Applicants did have possession of the claimed invention. Therefore, Applicants submit that the specification does meet the requirements of 35 U.S.C. § 112, first paragraph. Applicants respectfully request the withdrawal of this objection.

## **II. Rejection under 35 U.S.C. § 112, second paragraph**

Claims 7-12, 17-20, 23-24 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. In particular, the Examiner contends that the claims contain means plus function limitations but no corresponding structure found in the specification. Applicants traverse the rejection as follows.

Claim 7 recites, *inter alia*, an abnormal pattern candidate detection processing system comprising: "abnormal pattern candidate detecting means", "image output means" and "malignancy certainty degree calculating means". As indicated on page 1, lines 17-24, of the specification, processing systems are well known in the art to include computer aided medical image diagnosing systems, in which detection and processing operations are performed by a computer when an image signal is received (See also, page 55, lines 3-9). Some examples of the processing is described in the specification, such as iris filtering processing (using an iris filter) and morphological filtering processing (using a morphological filter) (Page 20, lines 10-13). For example, the processing is performed in accordance with a series of processing algorithms which are stored on the computer (Page 56, lines 16-24 and Page 59, lines 4-10).

A computer which stores algorithms for performing processing operations provides sufficient corresponding structure within the claims to point out and distinctly claim the subject matter of the invention. Further, the image output means is described on page 19, lines 11-13, of the specification to be an image displaying means, such as a CRT display device, a liquid crystal monitor, or a printing means, such as a laser printer.

Therefore, the Applicants respectfully request the withdrawal of this rejection, in view of certain embodiments as described above.

Applicants also request the withdrawal of the rejections to the remaining claims for analogous reasons as presented above.

**III. Rejection under 35 U.S.C. § 102(b) over U.S.P. 6,058,332 to Nishikawa**

Claims 1, 4-7, 10-20 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Nishikawa. Applicants traverse the rejection as follows.

**A. Claims 1, 7, 13 and 17**

Claim 1 recites, *inter alia*, “the step of calculating a degree of certainty about malignancy, which degree represents a level of possibility of a pattern being a malignant pattern, with respect to the abnormal pattern candidate, the calculation being made in accordance with an index value representing a feature of the abnormal pattern candidate and in accordance with a correlation between the index value and possibility of a pattern being a malignant pattern, which correlation has been obtained from clinical results”, which the Examiner asserts is disclosed by Nishikawa. Applicants respectfully disagree.

In particular, the Examiner alleges that column 33, lines 13-25, of Nishikawa discloses a calculation being made in accordance with an index value representing a feature of the abnormal pattern candidate and in accordance with a correlation between the index value and possibility of a pattern being malignant. Column 33, lines 13-25, of Nishikawa merely describes that the Artificial Neural Network (ANN) output can be transformed to a likelihood of malignancy by using maximum-likelihood estimated calculations. It seems the Examiner is alleging that the ANN is an index value representing a feature of the abnormal pattern candidate and that

Nishikawa discloses a correlation between the index value and possibility of a pattern being a malignant pattern. Nishikawa, however, describes ANN having an input layer with 8 input units, each reading one of the eight features of Table 1 and having an output layer having a single output unit (Col. 20, lines 26-39). In addition, Nishikawa discloses combining all the extracted features from the image by using the ANN to develop an estimate of the likelihood of malignancy (Col. 32, lines 12-20). In other words, each feature of Nishikawa is merely one factor in calculating the ANN output, which is then converted into a likelihood factor. Therefore, the index value (the ANN output) of Nishikawa differs from the index value of the present invention, which represents a detected abnormal pattern candidate. Additionally, no feature of an abnormal pattern candidate of Nishikawa provides a direct correlation and the possibility of a pattern being a malignant pattern in the calculation of a degree of certainty. Stated differently, the ANN-based value of Nishikawa correspond to a composite (network of data) and thus cannot correlate with the pattern candidate due to the intermingling of multiple factors. Moreover, such index value cannot be correlated to possibility of malignancy, wherein the correlation is provided in relation to clinical results. Thus, Nishikawa fails to disclose each and every feature of claim 1.

Applicants submit that claim 1 is patentable for at least these reasons

Also, since claims 7, 13 and 17 contain features similar to claim 1, claims 7, 13 and 17 should be patentable for reasons analogous to those presented above in conjunction with claim 1.

**B. Claims 4-6, 8-12, 14-16 and 18-20**

Applicants submit that claims 4-6, 8-12, 14-16 and 18-20 should be patentable at least by virtue of their dependencies upon claims 1, 7, 13 and 17, respectively.

**IV. Rejection under 35 U.S.C. § 103(a) over Takeo USPG PUB 2002/0062075 in view of U.S.P. 6,154,560 to Cothren et al. ("Cothren")**

Claims 1-2 and 7-8 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Takeo in view of Cothren. Applicants traverse this rejection.

**A. Claims 1 and 7**

Claim 1 recites, *inter alia*, "the step of calculating a degree of certainty about malignancy, which degree represents a level of possibility of a pattern being a malignant pattern, with respect to the abnormal pattern candidate, the calculation being made in accordance with an index value representing a feature of the abnormal pattern candidate and in accordance with a correlation between the index value and possibility of a pattern being a malignant pattern, which correlation has been obtained from clinical results, and the step of outputting at least the information for specifying the detected abnormal pattern candidate is a step of outputting information representing the degree of certainty about malignancy with respect to the abnormal pattern candidate together with the information for specifying the detected abnormal pattern candidate, which the Examiner concedes is not taught by Takeo. Therefore, the Examiner cites to Cothren to correct the deficiencies of Takeo. Amended claim 1 also recites that "the degree of certainty about malignancy is determined from a single index

value, which is obtained by combining a plurality of indices representing a plurality of feature measures of a calculation object region”.

In view of the foregoing, the method and system of the present invention calculates degrees of certainty regarding the malignancy of abnormal pattern candidates, based on correlations between likelihood ratios of Mahalanobis distances and probabilities of malignancy, derived from clinical results obtained by a great number of pathological tests and the like. That is, a graph, which is compressed into a one dimensional function, is generated having a single index value (e.g., the likelihood ratios of Mahalanobis distances) as its horizontal axis, and certainty of malignancy, which is the percentage that malignancy is present for the likelihood ratio for subjects of calculation, as its vertical axis. The certainty of malignancy, which is indicated by the vertical axis, is obtained from the single index value of the horizontal axis. That is, *the degree of certainty about malignancy is determined from a single index value, which is obtained by combining a plurality of indices representing a plurality of feature measures of a calculation object region* (see, p. 42, line 25 - 45, line 15 of the specification). Accordingly, the certainty of malignancy can be calculated stably, without singular values being generated. In addition, claim 1 requires *outputting information representing the degree of certainty about malignancy with respect to the abnormal pattern candidate together with the information for specifying the detected abnormal pattern candidate*.

Meanwhile, Cothren teaches the use of a look up table (or a common multidimensional table) (Col. 20, line 60 - Col. 21, line 5 and Table I). The parameters “correlation value”, “difference entropy value”, and “size of a node” are input to the table to calculate a probability

that the node is malignant. The probability is then displayed on a display. Table I of Cothren lists 68 combinations of the parameters for calculating the probability that nodes are malignant. Two examples of the calculation of probabilities that nodes are malignant are described from column 20, line 67 to column 21, line 11. However, the numerical values of the parameters listed in Table I do not increase nor decrease monotonously. Cothren does not provide a description regarding how the probabilities that nodes are malignant are calculated based on Table I. Further, there is no teaching or suggestion regarding the method described above, by which the degrees of certainty are obtained in the present invention. For example, the sizes of lymph node "Area (mm<sup>2</sup>) in Table I of Cothren are not directly related to the malignancies thereof, and therefore are not optimal for use as a single index. In addition, although Cothren appears to teach displaying the probability that nodes are malignant on the display 69, there is no teaching or suggestion regarding displaying the probability *along with data that specifies the position of abnormal pattern candidates*.

Therefore, in view of the above, Cothren fails to correct the deficiencies of Takeo. Applicants submit that claim 1 is patentable for at least this reason.

Also, since claim 7 contains features similar to claim 1, claim 7 should be patentable for reasons analogous to those presented above in conjunction with claim 1.

**B. Claims 2 and 8**

Applicants submit that claims 2 and 8 should be patentable at least by virtue of their dependencies upon claims 1 and 7, respectively.



**V. Rejection under 35 U.S.C. § 103(a) over Nishikawa in view of U.S.P. 6,266,435 to Wang**

Claims 3 and 9 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Nishikawa in view of Wang. However, Wang does not correct the deficiencies with regards to Nishikawa. Since claim 3 and 9 depend upon claims 1 and 7, respectively, Applicants submit that claims 3 and 9 are patentable at least by virtue of their dependencies.

**VI. Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

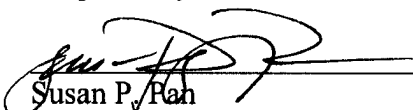
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